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SEP 1 6 2002

Attorney Docket No. 02481.1774-00000

HE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Group Art Unit: 1645 Paul HABERMANN et al. Examiner: UnknownTECH CENTER 1600/2900 Application No.: 10/076,634 Filed: February 19, 2002 NUCLEIC ACIDS, PROTEINS, For: AND PROCESSES FOR PRODUCING PROTEINS SUCH AS FUSION PROTEINS FOR THE SECRETION OF A PROTEIN OF INTEREST INTO BACTERIAL

Commissioner for Patents Washington, DC 20231

SUPERNATANTS

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed after three months of the filing date of this application, but, to the undersigned's knowledge, before the mailing date of a first Office Action on the merits.

Copies of the listed documents, including the copending applications discussed below, are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

FINNEGAN **HENDERSON** FARABOW GARRETT& DUNNER 些

U.S. Application No. 10/076,634 Attorney Docket No. 02481.1774-00000

The following commonly assigned, co-pending applications are brought to the attention of the Examiner:

U.S. Application No. 10/076,631, in the name of Paul HABERMANN, filed February 19, 2002, entitled "NUCLEIC ACIDS, PROTEINS, AND PROCESSES THEREOF SUCH AS PROCESSES FOR PRODUCTION OF SUPERSCRETABLE PEPTIDES AND FOR PARALLEL IMPROVEMENT OF THE EXPORTED FORMS OF ONE OR MORE POPLYPEPTIDES OF INTEREST"

U.S. Application No. 10/076,632, in the name of Paul HABERMANN, filed

February 19, 2002, entitled "NUCLEIC ACIDS, PROTEINS, AND PROCESSES

THEREOF SUCH AS USE OF FUSION PROTEINS WHOSE N-TERMINAL PART IS A

HIRUDIN DERIVATIVE FOR THE PRODUCTION OF RECOMBINANT PROTEINS VIA

SECRETION BY YEASTS"

Copies of these applications are attached.

Regarding the foreign language documents, Applicants note the following:

(1) DE 100 33 195 A1:

is accompanied by an English language abstract;

is cited and discussed in the present application beginning on page 3: and

is a family member of WO 02/04486 A2, submitted herewith, which includes an English language abstract and which corresponds to PCT/EP00/08537, which is cited and discussed in the present application beginning on page 3.

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP

U.S. Application No. 10/076,634 Attorney Docket No. 02481.1774-00000

- (2) DE 34 30 556 A1 is cited and discussed in the present application beginning on page 4.
- (3) EP 0 158 564 A1 is a family member of U.S. Patent No. 5,705,355 to TOLSTOSHEV et al., submitted herewith.
 - (4) EP 0 200 655 B1 includes English language claims.
- (5) EP 0 324 712 B1 includes English language claims and is cited and discussed in the present application beginning on page 4.
 - (6) EP 0 347 781 B1 includes English language claims.
- (7) EP 0 448 093 B1 includes English language claims and is cited and discussed in the present application beginning on page 20.
- (8) EP 0 468 539 B1 includes English language claims and is cited and discussed in the present application beginning on page 15.
 - (9) EP 0 549 915 B1 includes English language claims.
- (10) EP 0 775 710 A1 is a family member of U.S. Patent No. 6,103,502 to MÖLLER *et al.*, submitted herewith.
 - (11) WO 01/21662 A1 includes an English language abstract.
 - (12) WO 02/04486 A2:

includes an English language abstract;

corresponds to PCT/EP00/08537 which is cited and discussed in the present application beginning on page 3; and

is a family member of DE 100 33 195 A1, submitted herewith, which is accompanied by an English language abstract and which is cited and discussed in the present application beginning on page 3.

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

INFORMATION DISCLOSURE CITATION

OMB No. 0651-0011

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	Atty. Docket No.	2481.1774-00	Appln. No.	10/076,634	SEP 1 6 2002
ſ	Applicant	Paul HABERMANN et al.	·		
Ì	Filing Date	February 19, 2002	Group:	1645	TECH CENTER 1600/2900

	OTHER DOCUMENTS (Including Aut	hor, Title, Date, Pertinent Pages, Etc.)				
(PE vo	Dé et al., "Channel-forming properties from <i>Pseudomonas fluorescens</i> MFO 1995.	and structural homology of major outer membrane proteins and OE 28.3," <u>FEMS Microbiology Letters</u> , 127, 267-272,				
SEP 1 3 TOTE IN	Fürste et al, "Molecular cloning of the expression vector," Gene, 48(1), 119-	plasmid RP4 primase region in a multi-host-range <i>tacP</i> 131, 1986.				
Mare Thate dige	Griessbach et al., "Assay of Hirudin in Thrombosis Research, 37, 347-350, 1	Plasma Using a Chromogenic Thrombin Substrate," 985.				
	Price et al., "Expression, purification a machrophage colony-stimulating facto 293, 1987.	nd characterization of recombinant murine granulocyte-r and bovine interleukin-2 from yeast," <u>Gene</u> , 55(2-3), 287-				
	Rioux et al., "Genes on the 90-Kilobase Plasmid of <i>Salmonella typhimurium</i> Confer Low-Affinity Cobalamin Transport: Relationship to Fimbria Biosynthesis Genes," <u>Journal of Bacteriology</u> , 172(11), 6217-6222, 1990.					
	Rosenfeld et al., "Production and Purification of Recombinant Hirudin Expressed in the Methylotrophic Yeast <i>Pichia pastoris</i> , <u>Protein Expression and Purification</u> , 8(4), 476-482, 1996.					
	Shuttleworth et al., "Sequence of the gene for alkaline phosphatase from Escherichia coli Nucleic Acids Research, 14(21), 8689, 1986.					
	Wetekam et al., "The nucleotide sequence of cDNA coding for preproinsulin from the prima <i>Macaca fascicularis</i> ," Gene, 19(2), 179-183, 1982.					
	Weydemann et al., "High-level secretic processing of three different preprohir 377-385, 1995.	on of hirudin by <i>Hansenula polymorpha</i> —authentic udins," <u>Applied Microbiology and Biotechnology</u> , 44(3-4),				
	Winter et al., "Increased Production of Human Proinsulin in the Periplasmic Space of Escherichia Coli by Fusion to DsbA," <u>Journal of Biotechnology</u> , 84, 175-185 (2000).					
Examiner		Date Considered				
thro	al if reference considered, whether or no ough citation if not in conformance and n nmunication to applicant.	ot citation is in conformance with MPEP 609; draw line not considered. Include copy of this form with next				
Form PTO 1449	Patent and	Trademark Office - U.S. Department of Commerce				

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U.S. Application No. 10/076,634 Attorney Docket No. 02481.1774-00000

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 13, 2002

By: Steven J. Helmer

Reg. No. 40,475

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FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

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 Atty. Docket No.
 2481.1774-00
 Appln. No.
 10/076,634
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 Applicant
 Paul HABERMANN et al.
 TECH CENTER 1600/2900

 Filing Date
 February 19, 2002
 Group:
 1645

xaminer Initial*		Document Issue Date Number		Name		Class	Sub Class	Filing Date	
	\dagger	5,705,355	01/1998		Tolstoshev et al			0.000	
		6,103,502	08/2	2000	Möller et al.				
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		Document Number	ŀ	Public Da		Country	Class	Sub Class	Translation Yes or No
] .	DE 10033195A1		03/2002		Germany			Abstract
		DE 3430556A1		02/1986		Germany			
***		0 158 564 A1		10/1985		EPO			
		0 195 691 B1		09/1986		EPO			
	,	0 200 655 B1		04/1	995	EPO			Claims
=#		0 214 826 B1		03/1	987	EPO			
		0 324 712 B1		07/1	989	EPO			Claims
		0 347 781 B1		12/1	989	EPO			Claims
		0 375 437 B1		06/19	990	EPO			
	<u> </u>	0 419 504 B1		04/19	991	EPO			
	<u> </u>	0 448 093 B1		09/19	991	EPO			Claims
	<u> </u>	0 468 539 B1		01/19	992	EPO			Claims
·	Ŀ	0 489 780 B1		06/19	992	EPO			
·		0 511 393 A1		11/19	992	EPO			
		0 549 915 B1		07/19	993	EPO			Claims
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		WO 02/04486 A	2	01/20	002	WIPO			ABSTRACT